K083871

APR 15 2009

VII. SECTION 10 - 510(K) SUMMARY

This summary of 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR Part 807.92.

1. **Applicant's Name and Address**

Astra Tech Inc.
25 First Street
Cambridge, Massachusetts 02141
Telephone Number: 617-871-2783
Fax Number: 617-871-6607
Contact Person: Franklin Uyleman
Manager of Quality and Regulatory Affairs

2. **Name of Device**

Trade Name: Atlantis™ Straumann Bone Level Abutment
Common Name: Endosseous dental implant abutment
Classification Name: Endosseous dental implant abutment
21 CFR 872.3630 Product code NHA

3. **Legally Marketed Device to which Equivalence is claimed (Predicate Device)**

Manufacturer	Device	510(k) Number
Institut Straumann AG	SLactive Implants	K053088
Institut Straumann AG	P.0004 Implants	K062129
Institut Straumann AG	Straumann Narrow Neck	K060958
Atlantis Components Inc. (currently Astra Tech Inc.)	Atlantis™ Abutment for Straumann Interface	K050052
Atlantis Components Inc. (currently Astra Tech Inc.)	Atlantis™ Abutment in Zirconia	K052070

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4. **Description of the Device**

The devices covered in this submission are abutments which are placed into the dental implant to provide support for a prosthetic restoration. The subject abutments are indicated for cemented restorations. The **Atlantis™ Straumann Bone Level Abutment** and **abutment screw** are made from Titanium grade Ti-6A1-4V ELI (meets ASTM Standard F-136) for the 3.3mm, 4.1mm and 4.8mm sizes. In addition, the **Atlantis™ Straumann Bone Level Abutment** for the 4.1mm and 4.8mm sizes, also are made of the biocompatible material, yttria-stabilized tetragonal zirconia polycrystals (Y-TZP) (meets ISO Standards 6072 & 13356). The titanium and the zirconium abutments are placed over the implant shoulder and are mounted into the implant with a titanium screw.

The titianium abutments are compatible with Struamann Implants: Standard SLActive 3.3mm, 4.1mm and 4.8mm; and the Straumann Narrow Neck 3.5mm.

The abutments in zirconia are compatible with Straumann Implants: SLActive 4.1mm and 4.8mm

5. **Intended Use of the Device**

The devices covered by this submission are abutments which are placed into a dental implant to provide support for a prosthetic reconstruction. The Atlantis Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.

6. **Basis for Substantial Equivalence**

The **Atlantis™ Straumann Bone Level Abutments** in titanium are substantially equivalent in intended use, material, design and performance to the Straumann SLActive abutments cleared under K053088, K062129, and K060958, as well as the Atlantis Abutments for Straumann Interface cleared under K050052. Also, the **Atlantis™ Straumann Bone Level Abutments** in zirconium are substantially equivalent in intended use, material, design and performance to the Atlantis™ Abutments in Zirconium cleared under K052070.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 15 2009

Astra Tech Incorporated
C/o Ms. Betsy A. Brown
B.A. Brown & Associates
8944 Tamaroa Terrace
Skokie, Illinois 60076

Re: K083871
Trade/Device Name: Atlantis™ Straumann Bone Level Abutment
Regulation Number: 21 CFR 872.3630
Regulatory Class: II
Product Code: NHA
Dated: April 10, 2009
Received: April 13, 2009

Dear Ms. Brown:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if Known) K083871

Device Name: Atlantis ™ Straumann Bone Level Abutment

Indication for Use:

The Atlantis Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.

This device is compatible with the following manufacturers' implant systems:

The titanium abutments are compatible with the Straumann Implants: Standard SLActive 3.3mm, 4.1mm and 4.8mm and the Straumann Narrow Neck 3.5mm

The abutments in zirconia are compatible with the Straumann Implants: SLActive 4.1mm and 4.8mm.

Please note: This device may be used in an early load situation, but is dependent on the specific implant system and protocol used by the dental professional.
Highly angled abutments (i.e. 30 degrees) on implants with diameters less than 4 mm are intended for the anterior region of the mouth and are not intended for the posterior region due to limited strength of the implant.

Prescription Use X AND/OR Over-The-Counter Use____
(Part 21 CFR 801 SubpartD) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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